

§ 886.1

- 886.4390 Ophthalmic laser.
- 886.4392 Nd:YAG laser for posterior capsulotomy and peripheral iridotomy.
- 886.4400 Electronic metal locator.
- 886.4440 AC-powered magnet.
- 886.4445 Permanent magnet.
- 886.4570 Ophthalmic surgical marker.
- 886.4610 Ocular pressure applicator.
- 886.4670 Phacofragmentation system.
- 886.4690 Ophthalmic photocoagulator.
- 886.4750 Ophthalmic eye shield.
- 886.4770 Ophthalmic operating spectacles (loupes).
- 886.4790 Ophthalmic sponge.
- 886.4855 Ophthalmic instrument table.

Subpart F—Therapeutic Devices

- 886.5100 Ophthalmic beta radiation source.
- 886.5120 Low-power binocular loupe.
- 886.5420 Contact lens inserter/remover.
- 886.5540 Low-vision magnifier.
- 886.5600 Ptosis crutch.
- 886.5800 Ophthalmic bar reader.
- 886.5810 Ophthalmic prism reader.
- 886.5820 Closed-circuit television reading system.
- 886.5840 Magnifying spectacles.
- 886.5842 Spectacle frame.
- 886.5844 Prescription spectacle lens.
- 886.5850 Sunglasses (nonprescription).
- 886.5870 Low-vision telescope.
- 886.5900 Electronic vision aid.
- 886.5910 Image intensification vision aid.
- 886.5915 Optical vision aid.
- 886.5916 Rigid gas permeable contact lens.
- 886.5918 Rigid gas permeable contact lens care products.
- 886.5925 Soft (hydrophilic) contact lens.
- 886.5928 Soft (hydrophilic) contact lens care products.
- 886.5933 [Reserved]

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 33355, Sept. 2, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 886 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 886.1 Scope.

(a) This part sets forth the classification of ophthalmic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show

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merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an ophthalmic device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 33355, Sept. 2, 1987, as amended at 73 FR 34860, June 19, 2008]

§ 886.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section